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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/040,830      | 01/08/2002  | Gary E. Borodic      | 33677-00000         | 2713             |

38647 7590 01/18/2006

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EXAMINER

FORD, VANESSA L

ART UNIT PAPER NUMBER

1645

DATE MAILED: 01/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/040,830 | <b>Applicant(s)</b><br>BORODIC ET AL. |  |
|                              | <b>Examiner</b><br>Vanessa L. Ford   | <b>Art Unit</b><br>1645               |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 October 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/12/05</u> . | 6) <input type="checkbox"/> Other: _____  |

**FINAL ACTION**

1. This Office Action is responsive to Applicant's amendment and response filed October 12, 2005. Claims 1-15 have been cancelled. Claims 16 and 18 have been amended.

2. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.

***Objection Withdrawn***

3. In view of Applicant's amendment the objection claim 18, page 5, paragraph 4 is withdrawn.

***Objection/Rejection Maintained***

4. The objection to the specification is maintained for the reasons set forth on page 6, paragraph 5 of the previous Office Action.

The objection was on the grounds that the disclosure is objected to because of the following informalities: The use of the trademarks has been noted in this application. See for example, page 9. It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. Appropriate correction is required.

Applicant submitted an amendment to page 9 of the instant specification with the response to the non-final Office action filed in October 12, 2005. However, the amendment to the specification did not include the trademark symbols that are associated with trademarks. For example, <sup>TM</sup> or ®. The objection to the specification is maintained until the informalities to the specification are corrected.

5. The rejection under 35 U.S.C. 102(b) is maintained for claims 16-19 for the reasons set forth on pages 4-5, paragraph 4 of the previous Office Action.

The rejection was on the grounds that Binder teaches a method of treating pain caused by trigeminal neuralgia by delivering an invertebrate presynaptic neurotoxin (botulinum toxin A) to a mammal (see the Abstract). Binder teaches that the botulinum toxin A is administered to the muscles of the face, cranium and neck (see the Abstract). Binder teaches that neurotoxin can be administered in a dose up to about 1000 units although individual dosages of about 15-30 units are preferred and dosages of 2.5 to 5 units will have therapeutic efficacy. Binder teaches that the neurotoxin will be administered as a composition at a dosage that is proportionally equivalent to about 2.5 cc/100 units (see columns 5-6). The claim limitation "wherein the neuralgia is associated with trauma" would be inherent in the teaching of the prior art because trigeminal neuralgia is associated with trauma and pain. Binder anticipates the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's Arguments

A) Applicant urges Binder does not teach inherently or otherwise each and every element of the claimed invention. Applicant urges that Binder does not teach:

a) identifying a subject with facial pain caused by trigeminal neuralgia in need of treatment thereof;

b) that said subject is in need of treatment of the facial pain caused by trigeminal neuralgia;

c) multifocal injections of a therapeutically effective amount of botulinum toxin to an afflicted area of the face excluding the brow and the upper or lower eyelid; and

d) treating the facial pain caused by trigeminal neuralgia with botulinum toxin.

Applicant urges that the prior art has been improperly applied against the claims.

B) Applicant urges that Binder is directed to methods for the treatment of headache pain. Applicant urges that headache pain is not the same as facial pain caused by trigeminal neuralgia. Applicant directs the Examiner to Example 1 of Binder to support their position by pointing out that the example is directed to the reduction of headache pain. Applicant also pointed out that one of the patients of Example 1 was diagnosed as having trigeminal neuralgia and treatment with botulinum toxin reduced headache pain. Applicant urges that the prior art does not administer to subjects

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multifocal injections of a therapeutically effective amount of botulinum toxin to an afflicted area of the face excluding the brow and upper and lower eyelids, thereby reducing or eliminating facial pain caused by trigeminal neuralgia.

C) Applicant urges that the previous Office Action alleges that the prior art teaches a method of alleviating pain from local areas of the face including the relief of headache as well as trigeminal neuralgia by administration of botulinum toxin. Applicant urges that they have not been able to find that teaching in the prior art.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed October 12, 2005 have been fully considered but they are not persuasive.

A) It is the Examiner's position that the prior art teaches:

a) a patient that has trigeminal neuralgia and the art teaches that the patient has pain associated with trigeminal neuralgia (column 2, Table 1(b), and columns 6-8).

b) multifocal injections of therapeutically effective amount of botulinum toxin to an afflicted area of the face because Binder teaches that a therapeutically effective amount of neurotoxin (botulinum toxin) is administered by extramuscular injection to the perimuscular areas of the face, cranium and

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neck (column 4 and Figure 1). Binder also teaches that the most preferred target sites to deliver the neurotoxins are the bilateral temporal, frontal, glabella and suboccipital of the face (column 7).

c) that those of ordinary skill in the art will recognize that additional therapeutic benefits may be achieved through introduction of the presynaptic neurotoxins of the invention into musculature (column 6, lines 58-67 and column 7, lines 1-3).

Based on the teachings of the prior art one of skill in the art could reasonably conclude that the prior art teaches the claimed invention.

B) Although, Applicant has directed the Examiner to Example 1 (a section the patent that teaches the administration of botulinum toxin to reduce headaches in humans), it should be noted that the totality of the prior art reference should be considered. Binder states that "... those of ordinary skill in the art will recognize that additional therapeutic benefits may be achieved through introduction of the presynaptic neurotoxins into musculature "(columns 6-7). Binder also teaches that the most preferred target sites to deliver the neurotoxins are the bilateral temporal, frontal, glabella and suboccipital of the face (column 7). Therefore, one of skill in the art could reasonably conclude that botulinum toxin can be administered to a patient to treat conditions other than headaches.

C) To address Applicant comments regarding the examples of the prior art, it should be noted that Table 1(b) discloses that trigeminal neuralgia is associated with facial nerves (column 2). Binder states that "... those of ordinary skill in the art will recognize that additional therapeutic benefits may be achieved through introduction of the presynaptic neurotoxins into musculature "(columns 6-7). Binder further teaches that patients that have pain related to for example, trigeminal neuralgia was reduced (column 6). Therefore, one skilled in the art would recognize that botulinum toxin can be used to treat headaches as well as pain associated with trigeminal neuralgia.

There is nothing on the record to show that the claimed method differs from that of the prior art. Therefore, the teaching of Binder anticipates the claimed method.

### ***Status of Claims***

6. No claims allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any



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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


### ***Conclusion***

8. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Vanessa L. Ford  
Biotechnology Patent Examiner  
January 3, 2005

  
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